201-14472

NCIC HPV
Sent by: Mary-Beth Weaver

05/20/2003 10:06 AM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on Benzene,1 ,1'-[1,2-ethanediybis(oxy)]bis[2,4,6-tribromo- (CAS No.37853-59-1)

Richard_Denison@environmentaldefense.org on 05/19/2003 02:10:46 PM

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Subject: Environmental Defense comments on Benzene,1 ,1'-[1,2-ethanediybis(oxy)]bis[2,4,6-tribromo- (CAS No.37853-59-1)

(Submitted via Internet 5/19/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and rhenrich@glcc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Benzene,1,1'-[1,2-ethanediybis(oxy)]bis[2,4,6-tribromo- (CAS No.37853-59-1).

This chemical, abbreviated as BEOBTB, is sponsored by Great Lakes Chemical Corporation. It is sold under several different trade names, including Firemaster 680, and it is used primarily as a flame retardant in plastic products. Since the nature by which it is incorporated into specific plastic products is not provided, we assume that there is opportunity for environmental release and therefore human exposure.

The sponsor claims that no additional studies are needed to fulfill program requirements for the SIDS endpoints. However, the information presented in the test plan and robust summaries is not adequate for us to support such a conclusion. In particular, it may be necessary to conduct reproductive toxicity and chromosomal aberration studies, and also studies on hydrolysis rates, unless the sponsor can more fully justify its claim that these studies are not needed.

Specific comments are as follows:

1. The sponsor claims that no water hydrolysis studies are warranted because BEOBTB contains no hydrolyzable functional groups and a hydrolysis rate cannot be determined by the EPIWIN program. Yet one study conducted in 1977 reported that measurable hydrolysis occurs in hot water in 6 hours. The sponsor argues that this study was poorly conducted, but it is a published study in the scientific literature, and it does seem plausible that the ester linkages could be cleaved. We recommend that the sponsor clarify the hydrolysis issue by conducting a hydrolysis rate study under GLP.

2. BEOBTB apparently bioconcentrates but does not bioaccumulate, indicating that it is absorbed by fish but at some point absorption and elimination are in equilibrium; the maximum bioconcentration factor of 40 is indicative of moderate bioconcentration capacity. This finding does raise some concerns about fish contamination if environmental releases are occurring.

3. The sponsor proposes that chromosomal aberration studies are not needed because BEOBTB is not absorbed following ingestion. However, data presented in the test plan and robust summaries do show some degree of

absorption: BEOBTB causes an increase well above background in bromine content of various tissues. Therefore, we recommend that the sponsor conduct a chromosomal aberration study. This study could use an in vitro protocol not requiring sacrifice of animals.

4. There are two oral feeding studies presented in the robust summaries. The two studies resulted in vastly different bromine contents of tissues after apparently equivalent doses, and also yielded different toxicology results: hepatocellular lesions were seen in one study, but not the other. We also note that the purity of the test substance was not given in either study, suggesting that one of the studies may have used an impure form of the test chemical and/or their was an error in dosing. We are not recommending that an additional repeat dose study be conducted, but we are asking that the sponsor provide an explanation for the apparent discrepancies in the repeat dose studies.

5. The sponsor argues that reproductive studies are not needed because the developmental toxicology studies were negative, no lesions of the reproductive tract were observed in the repeat dose studies, and the chemical is not absorbed. However, as noted earlier, BEOBTB is absorbed, and the repeat dose studies are ambiguous; moreover, these studies did indicate pituitary and uterine lesions in females, which were discounted without reason by the sponsor. Unless the sponsor can provide a convincing explanation as to why the lesions were discounted, then we recommend that a reproductive toxicity study be conducted on BEOBTB.

Thank you for this opportunity to comment.

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